

Food and Drug Administration

Name of Committee: Anesthetic and Life Support Drugs Advisory Committee.

Date and Time: The meeting will be held on September 13 & 14, 2001, 8 a.m. to 5 p.m.

Location: University of Maryland, Shady Grove Campus,

Agenda: On both days the committee will discuss the medical use of opiate analgesics in various patient populations, including pediatric patients and patients with chronic pain of nonmalignant etiology, as well as the risk to benefit ratio of extending opiate treatment into these populations. It will also address concerns regarding the abuse potential, diversion and increasing incidence of addiction to opiate analgesics, especially to the modified release opiate analgesics.

Public Participation: The entire meeting is open and the public is invited to attend without pre-registration. In addition, a portion of the meeting, open-public hearing, is set aside so that the public may present relevant views to the committee. This portion of the meeting will be held from approximately 1 p.m. to 2 p.m. each day.

IF YOU WISH TO SPEAK AT THE OPEN PUBLIC HEARING

Please submit a statement of your position and how we might contact you before the meeting please e-mail the statement to topperk@cder.fda.gov or fax the statement to (301) 827-6801. **The statements must be received by August 17, 2001.** Please limit your presentation to 3 minutes. Any statements received after the deadline will be posted to the docket but will not be sent to the committee nor will you be scheduled time to speak.

IF YOU WISH TO SEND A STATEMENT FOR THE RECORD

All the letters already received will be posted under **docket number 01N-0256**. If you wish to send in a statement to be posted please go to:

<http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm> select "Submit electronic comments" and follow the prompts.

Letters/statements may be mailed to:

Kimberly Topper
Food and Drug Administration, CDER,
Advisors and Consultants Staff, HFD-21
5600 Fishers Lane,
Rockville Maryland 20857

Due to the overwhelming interest in this meeting and time constraints - no statements will be read into the transcript by FDA staff. All statements received before the August 17th deadline will be available to the committee in advance

FINDING INFORMATION ABOUT THE MEETING ON THE WEB

Because this **meeting is not aimed at a single specific drug** but to discuss the class of opiate analgesic drugs the background information will be posted shortly after it is sent out to the members. All the information that is available for this meeting will be posted on the FDA web site at: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> (Click on the year 2001 and scroll down to Anesthetic and Life Support Drugs meetings.) This is the same web site where you can find the minutes, transcript, and slides from the meeting. This material is generally posted about three weeks after the meeting.

We maintain our FDA Advisory Committee Information Line at 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12529. Please call the Information Line for up-to-date information on this meeting.

Some of you received incorrect information about contacting me to arrange for TV or tape coverage. There are 3 private companies that provide this service and you must contact them directly at:

Video on Location
Jim or Alex
(301) 984-5823

Video Vision
Simone
(301) 438-8724

FDC Reports (Pink Sheet)
Brad
(301) 664-7211

Hotel reservations must be made on your own. There are 6 major hotel chains in the Gaithersburg Maryland area. FDA **DOES NOT** pay for Open Public Hearing Speakers.